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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,182	10/05/2005	Marcia L Kalish	6395-67856-06	6209

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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,182	KALISH ET AL.	
	Examiner	Art Unit	
	BO PENG	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-29,36 and 41-60* is/are pending in the application.

4a) Of the above claim(s) *47-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-29,36,41-46 and 55-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 15, 2009, has been entered.

2. Claims 1-25, 30-35 and 37-40 have been cancelled. New Claim 60 has been added. Claims 26-29, 36 and 41-60 are pending. Claims 47-54 were previously withdrawn from consideration. Claims 26-29, 36, 41-46 and 55-60 are considered in this Office action. Applicant elected species of SEQ ID NOs: 1 and 14.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **(New rejection-necessitated by the amendment)** Claims 26-29, 36, 41-46 and 55-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 26 and 29 are indefinite. Claims 26, 29 recite: "... wherein the detection multiple antigenic peptide consists of a core matrix and at least two linear antigenic

sequences..., each linear antigenic sequence is less than 16 amino acid residues...". The "close ended" transitional phrase "consists of" indicates that the claimed peptide is "close" to other components. However, "at least two linear antigen sequences" means "open" to additional antigen sequences. "... each linear antigenic sequence is less than 16 amino acid residues..." indicates a range of sequences from 0 to 16 amino acids. It is not clear how "the detection multiple antigenic peptide consists of" "at least two linear antigenic sequences..., each linear antigenic sequence is less than 16 amino acid residues...". Given the different scopes within Claims 26 and 29, one of ordinary skill in the art cannot be reasonably apprised of the metes and bounds of the invention. This rejection affects all dependent claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. (**Prior rejection-withdrawn**) The rejection of Claims 26-29, 36, 41-46 and 55-59 under 35 U.S.C. 103(a) as being unpatentable over Simon, *et al*. (AIDS Res. And Hum Retroviruses, 17(10):937-952, 2001, cited in IDS); in view of Guertler (6,566,513), Tam (PANS, 1988, cited in IDS), Kim (2001, cited in IDS), **is withdrawn** in view of the amendment to the claims. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection set forth below.

8. (**New rejection**) Claims 26-29, 36, 41-46 and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon, *et al*. (AIDS Res. And Hum Retroviruses, 17(10):937-952, 2001, cited in IDS), Tam (1) (J. Immunological methods, 124:53-61, 1989), Mabrouk (6,379,679), Tam (2) (US 5,580,563) and Kim (2001, cited in IDS).

9. Claims 26-29, 36 and 46 are drawn to an immunoassay construction to detect and differentiate amongst various SIVs, comprising a first substrate of a plurality of **detection** multiple antigenic peptides (MAPs) derived from the immunodominant region of SIV **gp36/41**, and a second substrate of a plurality of **differentiation** MAPs derived from **gp120 V3** loop, wherein the detection MAP and the differentiation MAP bonded to the core matrix by β-Ala and d-Asp, each linear antigenic sequence is less than 16 amino acid residues, wherein at least one of the MPAs represent at least one SIV;

10. Claims 28 and 57 require that each linear antigenic sequence of MAPs **comprises** 5-15 amino acid residues;

Claims 41-44, 55, 56, 58 and 60 require that the linear antigenic sequence of the

detection MAP is SEQ ID NO: 1; and/or the linear antigenic sequence of the differentiation MAP is SEQ ID NO: 14;

Claims 45 and 59 require that the immunoassay of Claim 26 or 29, wherein the detection MAP and differentiation MAP each comprise **four** linear antigenic sequences bound to their respective matrix.

MAPs are defined in the specification as each peptide conjugated to a core consisting of 2^x amino groups of lysine covalently attached to the *C*-terminus of either a detection or differentiation peptide thus presenting 2^x copies of each peptide per core.

11. Simon teaches an enzyme immunoassay in an ELISA format for detecting and differentiating amongst various SIVs using synthetic peptides derived from SIV gp36/41 as detection antigenic peptides, and peptides derived from SIV gp120 V3 loop as differentiation antigenic peptides, see e.g. Abstract. As shown in Table 1, Simon teaches a SIVcpz gp41/36 peptide detection antigenic peptide, which **comprises** a linear antigenic sequence 100% identical to amino acids 1 to 9 of the instant detection peptide SEQ ID NO: 1, and a SIVcpz V3 peptide **comprises** a linear antigenic sequence 100% identical to the instant differentiation peptide SEQ ID NO: 14, as shown in the sequence alignment below:

```
Simon gp41/36       LAVERYLQDQQILGLWGCSGKAVC
SEQ ID NO: 1                      WGCSGKAVCYT


Simon V3 peptide:   NNTRGEVQIGPGMTFYNIENVVGDTRSA
SEQ ID NO: 14          RGEVQIGPGMTFYNI
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12. Simon teaches that both gp41/36 detection peptides and V3 differentiation

peptides are effective for detecting and differentiating different strains of HIV and/or SIV, see e. g. Abstract. The gp41/36 detection peptides correctly identified all the test samples, with 98% specificity. The V3 differentiation peptides discriminated 206 HIV-1 group M, 98 group O, 12 group M-t-O, and 128 HIV-2 sera. In the primate field evaluation panel, both gp41/36 and V3 detected and discriminated all the WB-positive samples originating from monkeys infected with SIVcpz, SIVagm-ver, SIVmnd-1, SIVmnd-2, SIVdrl, or SIVsun. Simon teaches that this detection and differentiation ELISA prove is useful for studies of lentivirus prevalence and diversity in human and non-human primates, and may also have the potential to detect previous un-described SIVs (see e.g. Abstract).

13. Simon does not teach an enzyme assay in MAP format comprising multiple SIV gp41/36 detection and V3 differentiation peptides.

14. Tam (1) teaches MAP enzyme immunoassay construct, which contain a core matrix and multiple antigen peptides of 12-17 amino acids, see e.g. Abstract. The core matrix comprises β-Ala and various arrangements of lysyl spacer. Tam teaches that immunoreactivity of MAP-containing peptides is superior to that of monomeric peptides conjugated to a protein carrier. Therefore, MAP provides a novel approach to increase detection sensitivity of synthetic peptides in solid-phase immunoassays.

15. Using a model short peptide of 13 amino acid residues derived from the V3-1oop of HIV-1 gpl20, Kim demonstrates that MAPs composed of two, four, and eight branches of the HIV-1 V3 monomeric peptide have better antigenicity than monomeric peptide and the tandem repeats (Abstract).

16. Mabrouk teaches that incorporating D-amino acids in MAP construct results in a longer life time of MAP in vivo, see e.g. Para 3 and 4, col. 2.

17. Tam (2) teaches MAP constructs, which comprise an antigen peptide and a hydrophilic linker, wherein peptides bind to the core matrix by β-Ala and D-Ser, see e.g. Fig. 10B, Para 4, col. 15, and Para 4 and 5, col. 16.

18. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the detection and differentiation enzyme immunoassay of Simon by using a MAP format as taught by Tam and Kim to increase the sensitivity of the assay.

MPEP § 2144.06 recites the conclusions of In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA): "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose…[T]he idea of combining them flows logically from their having been individually taught in the prior art."

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

In the present case, the skilled artisan would have been motivated to use MAP format of detection/differentiation peptides of the prior art in an enzyme immunoassay for detecting SIVs, and have a reasonable expectation of success, given the utility of gp41/36 immunodominant region for detection of SIVs and highly variable and serogroup specific gp120 V3 loop for discrimination of SIV serogroups, as taught by Simon, given the successes of detection/differentiation peptides of the prior art in detecting SIV as shown by Simon, and also given that MAP constructs can increase sensitivity of the assay as

taught by Tam and Kim. One of ordinary skill in the art would also incorporate a D-amino acid, such as D-Asp, in core matrix, given that incorporating D-amino acids can increase the life time of MAPs as taught by Mabrouk. It is within the ability of one of ordinary skill in the art to make and to optimize MAP constructs by changing the sizes of antigenic peptide sequences, or by using other amino acids in the spacer as functional alternatives, as illustrated by Tam (1)(2), Mabrouk and Kim. Thus, the instant invention was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

19. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648